

MAY 24 2000



**Oncology Systems**  
3100 Hansen Way  
Palo Alto, CA 94304-1038  
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tel +1 650 493 4000  
www.varian.com

**Premarket Notification [510K] Summary  
as required by 21 CFR 807.92**

**Date Summary was prepared:**

March 16, 2000

**Submitter's Name:**

Varian Medical Systems  
3100 Hansen Way  
Palo Alto, CA 94304

**Contact Person:**

Linda S. Nash  
Corporate Director, Regulatory Affairs and Quality Assurance  
Phone (650) 424-6990  
FAX (650) 855-7364  
E-Mail linda.nash@os.varian.com

**Device Name:**

ProtonVision 7.0

**Classification Name:**

Medical Charged Particle Radiation Therapy, Accessory

**Predicate Device:**

CadPlan 6.0, K992753  
SomaVision 6.0, K992751

**Product Description:** The Varian ProtonVision is a computer-based device used for calculating and displaying prospective or verification treatment plans for particular patients undergoing a course of proton therapy. The system consists of a computer with graphics display and plotter output. As a SomaVision (K992751) option, ProtonVision provides the capabilities of diagnostic image analysis, contouring and segmentation. In addition to SomaVision, ProtonVision provides tools for proton energy range estimation, proton dose calculation and dosimetric plan review. ProtonVision integrates proton treatment planning with Varian Vision applications.

**Intended Use:** Varian ProtonVision device is a treatment planning system used for diagnostic image analysis, contouring & segmentation, proton energy range estimation, proton dose calculation and plan review.

**Technological Characteristics:**

See the attached "Specification Comparison Chart", Tab G.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 24 2000

Linda Nash  
Varian Medical Systems  
3100 Hansen Way  
M/S H055  
Palo Alto, CA 94304-1129

Re: K000922  
Proton Vision V7.0  
Dated: May 2, 2000  
Received: May 5, 2000  
Regulatory class: II  
21 CFR 892.5900/Procode: 90 MUJ

Dear Ms. Nash:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Daniel G. Schultz, M.D.  
Captain, USPHS  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure(s)

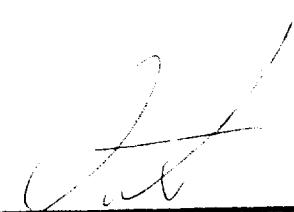


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## INDICATIONS FOR USE STATEMENT

The Varian ProtonVision device is used to plan proton radiation therapy treatments employing proton accelerators with energies from 70 to 235 MeV. ProtonVision will plan the 3D radiotherapy proton treatment approaches without compensators to rectangle and circular fields, and regular and irregular fields using customized blocking. ProtonVision includes also tools for treatment preparation (diagnostic image analysis, contouring & segmentation) and plan review.

As part of the Varis Vision System, ProtonVision integrates proton treatment planning in the overall therapy process, while taking advantage of the Varian Vision database.

  
\_\_\_\_\_  
(Division Sign-Off)

Division of Reproductive, Abdominal, **ENT**,  
and Radiological Devices

510(k) Number K000922

✓  
**Prescription Use** \_\_\_\_\_  
(Per 21 CFR 801.109)